

The present invention teaches a process for making a dried, modified cyclodextrin product with improved dusting and aqueous dissolution properties.

Modified cyclodextrins have conventionally been dried using a spray dryer resulting in a powder having a particle size less than 100 microns. This small particle size leads to dusting problems and to difficulty in water dissolvability, often resulting in clumps (page 2, par. 2).

The present invention overcomes the problems associated with the spray dryer by employing a double-drum dryer. A double-drum dryer produces a modified cyclodextrin product composed of flake-shaped particles, rather than bead-shaped particles. Further, the modified cyclodextrin product formed using a double-drum dryer is more porous than the spray dried product and results in a larger particle size than the spray dried product. All of these improved characteristics of the modified cyclodextrin product dried using a double-drum dryer contribute to the enhanced dusting and dissolving properties mentioned above.

Claims 1-5 had been rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al (US 6,153,746) in view of Walsh (US 5,980,971). The Examiner stated that Shah teaches that a solution

of sulfoalkyl ether cyclodextrin can be isolated by vacuum drum drying. The Examiner also stated that Walsh teaches that single and double drum dryers are well known to be interchangeable, and it would have been obvious to one of skill in the art to substitute the vacuum drum dryer used to recover the modified cyclodextrin of Shah with a double drum dryer as disclosed in Walsh.

Although Walsh does in fact state that single and double drum dryers are interchangeable (col. 6, line 8), Walsh is not directed to a method of drying a modified cyclodextrin. Walsh instead discloses processes for the preparation and manufacture of dried legumes to make whole bean and bean paste food products (Abstract). It would not be obvious to one of skill in the art to substitute a double drum dryer for a vacuum drum dryer when drying a modified cyclodextrin based solely on the fact such a substitution can be made to dry a bean food product. Thus, Applicants respectfully submit that a combination of the Walsh patent and the Shah patent is improper, since they do not contain analogous subject matter.

The Examiner additionally stated that Walsh teaches the preferred product size of the claim 5. Column 6, lines 14-16 state that the preferred film thickness of the Walsh product is between 0.001 and 0.25 inches (25 microns and 6250 microns). Column 6, lines 39-41 also state that the preferred size of flakes resulting

from the film are between 0.5 inches in size and flakes that would pass through size 10 mesh. In contrast, the claims of the present Invention recite the modified cyclodextrin product having a particle size of between about 20 microns and about 200 microns. In the event that the Examiner continues to assert that the Walsh patent can be combined with the Shah patent, even though pertaining to non-analogous subject matter, applicants submit that the broad range of product size taught in Walsh does not render obvious the much narrower particle size of the present invention.

Claims 6-11 had been rejected under 35 U.S.C. 103(a) as being unpatentable over Shah in view of Walsh and in further view of Giacobello (US 4,127,944). The Examiner recognized that the subject matter of claims 6-11 is identical to the subject matter of claims 1-5, except for the addition of the term "agglomerated" to describe the modified cyclodextrin product. Applicants therefore raise the same arguments discussed above in reference to claims 1-5. However, with respect to claims 6-11, the Examiner has additionally cited Giacobello as teaching the use of a vacuum chamber to improve the agglomeration of a dried product.

The Examiner had cited column 10, lines 27-34 of Giacobello which states that enclosing a drum dryer in a vacuum chamber "will ordinarily hasten the drying process and in some instances lead to

still further improved agglomeration of the dried product with consequent production of less fines while maintaining high absorbent properties." Applicants assume that the Examiner has cited this quotation for the suggestion that the product particle distribution of claim 7 can be met by enclosing a drum dryer in a vacuum chamber.

Respectfully, applicants submit that this quotation does not render obvious the particle size distribution of the present invention. First, the present invention does not utilize a vacuum chamber to surround a drum dryer, the claimed particle size distribution is achieved without the use of a vacuum chamber. Second, applicants do not believe that the broad, conclusory statement 'quoted from Giacobello can render obvious the specific particle size distribution as claimed. It is therefore believed to be improper to reject claims 6-11 based on a combination of Shah, Walsh, and Giacobello.

Claims 12-18 had been rejected under 35 U.S.C. 103(a) as being unpatentable over Majid et al (US 5,070,081) in view of Shah. In a manner similar with Giacobello, the Examiner stated that Majid teaches that the size of the agglomerates can be controlled by agitation and by varying the amount of added water.

Applicants submit that this teaching in Majid does not suggest the particle size distribution of claim 12. Majid is not directed to producing a dried cyclodextrin product in a manner similar to that of the present invention, in fact, Majid does not even mention cyclodextrins.

According to Example 1 of Majid, micro-agglomerates of about 1 mm in size are formed by agitation. There is no suggestion to one of skill in the art to produce dried modified cyclodextrins between about 20 microns and about 200 microns from the teaching that 1 mm agglomerates can be further agitated to decrease the agglomerate size. Further, the present invention deals with double drum drying, not agitation. In these respects, applicants believe the rejection based on Majid should be removed.

On page 2 of the Office Action, the Examiner stated that use of the term "modified" in claims 1, 7, and 12 renders the claims indefinite, since the term "modified" is a relative term. Applicants direct the Examiner's attention to page 1, paragraph 3 to page 2, paragraph 1, where an explanation of a "modified" cyclodextrin is given. A modified cyclodextrin is made in a reaction between a cyclodextrin and a chemical reactant. It is conventional to modify the cyclodextrin to increase its water solubility. Further, page 5, paragraph 4 states that the

modification reaction is conducted in a conventional way using conventional equipment and on page 6, line 5, an example of a conventional modified cyclodextrin is given, i.e. hydroxypropylated beta-cyclodextrin. As the Examiner may know, the term "cyclodextrin derivative" is also used for such cyclodextrins, see, for example, Shah column 1, lines 46-56. Consequently, applicants submit that one of reasonable skill in the art would readily recognize a "modified" cyclodextrin.

Claims 8-11 had been rejected as being a substantial duplicate of claims 2-4 and 6. Applicants have herein amended the dependency of claims 8-11. Claims 8-9 and 11 are now dependent upon claim 7, rather than claim 1, while claim 10 is now dependent upon claim 9, rather than claim 3.

Claim 6 and claim 11 lack antecedent basis based on the use of the term "method", since the term "method" does not appear in claims 1 and 7 from which they are dependent. As correction, the term "method" in claims 6 and 11 has thus been amended to read "process".

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance and such action is respectfully requested. A one-month extension of time is hereby

requested. Form PTO-2038 is enclosed to cover the appropriate fee. Should any additional fees or extensions of time be necessary in order to maintain this application in pending condition, appropriate requests are hereby made and authorization given to debit account #02-2275.

Respectfully submitted,

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Marked-up Copy of Amended Claims

- 6. (Amended) The [method] process of claim 1 wherein said aqueous solution has a solids content of greater than or equal to about 45% by weight.
- 8. (Amended) The process of claim [1] 7 wherein said cyclodextrin is a hydroxypropylated beta-cyclodextrin.
- 9. (Amended) The process of claim [1] 7 wherein said drum dryer has steam-heated drums rotated at about 1 to about 5 revolutions per minute.
- 10. (Amended) The process of claim [3] 9 wherein said drums are heated with steam at a pressure of about 100 psig.
- 11. (Amended) The [method] process of claim [1] 7 wherein said aqueous solution has a solids content of greater than or equal to about 45% by weight.